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Title:

**Safety and Efficiency of Procedural Sedation and
Analgesia (PSA) conducted by Medical Officers in a Level
One Hospital in Cape Town**

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In partial fulfilment of the requirements for the Mimed (Family Medicine)

*This research report is based on independent work by above mentioned candidate;
and neither the whole work, nor any part of it has been, is being, or is to be
submitted for another degree to any other university. The work has not been
published prior to registration for the abovementioned degree.*

Cape Town, 26th October 2011

Signature:

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Part A-Research proposal

Introduction

Procedural sedation and analgesia (PSA) is defined as a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function.⁽¹⁾ It was previously referred to as conscious sedation.

This technique is used in the emergency department for the performance of painful or uncomfortable procedures. It has been used for setting fractures, draining abscesses, reducing dislocations, performing endoscopy, imaging procedures, dilatation and curettage for evacuation of retained products of conception (D & C), cardioversion⁽²⁾ and during dental procedures.

In recent years PSA has gained popularity for a number of reasons, amongst which are improved patient-outcomes & cost-containment benefits, development of newer, better and safer drugs and techniques and better practitioner skills⁽³⁾. PSA is well perceived by patients⁽⁴⁾. Patient demand for this cost-effective and time-saving technique that offers the patient a reduced duration of hospital stay is increasing.

Rationale

The author's research was prompted by her experience that pain relief is often not a priority for the medical and nursing staff, despite the fact that pain is often the reason why the patient attends the health facility. In fact pain is the most common presenting symptom in the Emergency Department (ED). More than 60 percent of ED patients have pain as their main symptom or a major part of their symptoms⁽⁵⁾. This seems to be a global phenomenon.

While the patient's main agenda is to obtain pain relief, the physician is focused on diagnosis and treatment of the underlying disease process. This leads to discordance between the expectations of the patient and the focus of the health care provider.

A review of multiple publications, published in “Pain Management” has identified a number of causes for poor management of painful conditions in the ED: failure of ED staff to acknowledge pain, failure to assess initial pain, failure to have pain management guidelines in ED, failure to document pain and to assess treatment adequacy, and failure to meet patient’s expectations. The barriers that preclude emergency physicians from proper pain management include ethnic and racial bias, gender bias, age bias, inadequate knowledge and formal training in acute pain management and opiophobia of hospital staff⁽⁶⁾.

The author’s interest in procedural pain and pain relief in particular was sparked by witnessing painful procedures being performed in Emergency Departments on children and adults without administration of any analgesia and/ or sedation support.

Being able to safely relief pain that comes with such procedures, and provide a degree of immobility, not only leads to greater patient satisfaction and less post-traumatic stress, but also to easier working conditions for the ED doctor carrying out the procedure in question⁽⁷⁾.

Literature search

A pubmed search on English language articles between 1990 and April 2010 was performed using combinations of the key words “conscious sedation”, “moderate sedation”, “deep sedation”, “procedural sedation”, “conscious sedation versus general anaesthesia”, “procedural sedation versus general anaesthesia”, “moderate sedation versus general anaesthesia”, “deep sedation versus general anaesthesia”, “cost”, “cost analysis”, “cost comparison”, “economy”, “incomplete abortion”, “missed abortion”, “miscarriage”, “Ketamine”, “Midazolam”, “Opioids”, “Propofol”, “Ketofol”, “day case surgery”, “efficacy”, “safety”, “adverse events”, “side-effects”, “complication”, “morbidity”, “mortality”, “analgesia”, “sedation”, “emergency department”, “emergency department analgesia”, “interventional pain management”, “dilatation and curettage”, “surgical management of

missed abortion”, “anaesthetic management of missed abortion”, “South Africa” and “family physician”. Terms were then exploded as appropriate.

Lack of analgesia in the ER setting

An American study found that amongst 1727 procedures performed in the emergency department of a paediatric department with 20,000 patient visits per year, few to no patients undergoing venipuncture, intravenous catheter placement, fingersticks, intramuscular or subcutaneous injections, urethral catheterization, or nasogastric tube placement received pain management. Nearly all patients undergoing fracture reductions received procedural sedation with ketamine, and most of the lacerations repaired with sutures and nail avulsions received injected local anaesthetic. Pain management of abscess incision and drainage and lumbar punctures was more variable. For lumbar punctures, of the patients aged 4 months or younger only 29% (7/24) had pain management documented ⁽⁸⁾.

All too often physical restraint of children and adults is still seen and considered an appropriate form of immobilization for painful or anxiety-provoking procedures.

Effects of oligoanalgesia

Studies have shown that as a result of poor (procedural) analgesia, children become more anxious for further procedures and sensitized to pain in a way that decreases their pain threshold in later life ⁽⁹⁾. Stress associated with painful procedures can influence physiological, social and cognitive outcome ⁽¹⁰⁾. Studies have concluded that procedural pain and distress, can endure in memory, resulting, for example, in disturbances of feeding, sleeping, and the stability of the state of arousal. It is known today that early experiences of pain may produce permanent structural and functional reorganization of developing nociceptive neural pathways, which in turn affects future

experiences of pain ⁽¹¹⁾ and have emotional and psychological implications for children and families ⁽¹²⁾.

To put it simply, it is inhumane to allow any individual to suffer pain unnecessarily, when most emergency departments (ED) have the equipment and drugs to provide safe and appropriate analgesia to their patients.

Adverse effects of PSA

The use of PSA does carry some inherent risks. Nausea and vomiting are not uncommon with sedation agents such as Nitrous Oxide ⁽¹³⁾ or Ketamine. The most serious adverse outcome of any form of paediatric (and adult) sedation is respiratory compromise with subsequent hypoxaemia and its related consequences ⁽¹⁴⁻¹⁶⁾

Medical statistics differ with regards to numbers of adverse effects (AE) with conscious sedation, depending on what drugs are used and what is classified as an adverse effect.

Citation	Design	PSA Drugs used	Results	Other findings
Pitetti RD et al, Arch Pediatr Adolesc Med. 2003 ⁽¹⁷⁾	Prospective descriptive study of 1244 PSA events in 1215 children and young adults between 2 months and 19.4 years	IV fentanyl/ midazolam in (n=734) IV Ketamine midazolam, atropine (n=293) IM ketamine, midazolam, atropine (n=82) No non-parenteral sedation	Successful PSA in 1177 of 1194 PSA events (98%). 207 of 1161 (17.8%) adverse events, of which 93% (193 subjects) had hypoxia (Sats< 93%), treated with oral airways, reversal agents, bag-mask ventilation, followed by vomiting in 6.2% (13 patients)	No serious adverse effects, No mortality
Mark G, Roback, al; Acad Emerg Med 2005 ⁽¹⁸⁾	A retrospective comparative analysis of 2500 ED patients age 19 days to 32 years. Comparison of common parenteral drugs	Ketamine (n=1492); Ketamine/ Midazolam (n=299) Midazolam / Fentanyl (n=336); Midazolam (n=260) Others (n=113) IV (n=2279); IM (n=221) No non-parental sedation	458 adverse events in 426 patients (17%); of these 201 (44%) with resp adverse event; 175 (38%) with vomiting	Midazolam/ fentanyl group associated with increased risk of resp. events; Ketamine associated with vomiting. No Mortality

Pena BM, et al. Ann Emerg Med.1999 ⁽¹⁹⁾	Prospective descriptive study of 1180 ED patients, under 21 years, receiving PSA	Parenteral and non-parenteral sedation for painful procedures and imaging	27 of 1180 (2.3%) patients experienced adverse events, 16 of which had respiratory adverse event, the rest vomiting. Hypoxia defined as Sats< 90%	No serious complications. Lower number of side effects possibly due to inclusion of non parenteral sedation and less strict definition of hypoxia;
Cote CJ, et al. Pediatrics.2000 Apr. 105(4): 805-814 ⁽²⁰⁾	Critical Incidence Analysis of 118 adverse sedation events collected from various national (USA) sources.	Variety of PSA medications	95 incidences with consensus agreement: 51 deaths, 9 neurol. injury, 21 prolonged hospitalization; 14 no harm;	Adverse outcomes (permanent neurol. injury or death) associated with: non-hospital based facility, inadequate monitoring and presedation evaluation
National patient safety agency, NHS, 09 December 2008 ⁽²¹⁾	Critical Incidence Analysis of 498 adverse sedation events (UK) involving iv midazolam;	IV midazolam	3 deaths; 48 patients sustained moderate harm; 447 patients with no or low harm	Medication errors (dosages) due to problematic packaging and lack of staff training were main contributors to poor outcome.
Green SM, et al. Ann Emerg Med. 2009 Aug; 54(2):158-68. ⁽²²⁾	Patient data Meta analysis of 8282 paediatric ketamine sedations; Multiple regression analysis to determine clinical predictors of airway and respiratory adverse events	Ketamine sedation	Airway and respiratory adverse event rate of 3.9%	Predictors of adverse respiratory events: -Age < 2yrs or >13 yrs; -High iv dosing of ketamine (>2.5mg/kg initially or > 5mg/kg total dose); -Co-administered Benzodiazepines or anticholinergics -Underlying physical illness; -Oropharyngeal procedures; -IV vs IM route

Guidelines for PSA

In order to keep adverse effects of PSA to a minimum, many specialty societies and regulatory bodies have published guidelines for procedural sedation and analgesia each designed to address their specific priorities. Factors like medication errors or other human mistakes can probably never be fully avoided. However, most issues associated with adverse outcomes have been addressed in all of the well-known guidelines. The issues that are addressed include presedation patient assessment, monitoring of the patient,

appropriate skills of sedationist as well as facilities and minimum equipment requirements. The most widely circulated guidelines were produced by

- 1) The American Society of Anaesthesiologists ⁽²³⁾,
- 2) The American College of Emergency Physicians ⁽²⁴⁾ and
- 3) The American Academy of Paediatrics ⁽²⁵⁾.

While South Africa has its own set of guidelines, they are not regularly utilised. This was demonstrated by a recent study of PSA in EDs of the Western Cape ⁽²⁶⁾.

The practice guidelines for sedation and analgesia by non-anaesthetists ⁽²²⁾ recommend that “individuals responsible for patients receiving sedation-analgesia should understand the pharmacology of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines. Individuals monitoring patients receiving sedation/analgesia should be able to recognize the associated complications. At least one individual capable of establishing a patent airway and positive pressure ventilation should be present whenever sedation analgesia is administered.”

An ACLS (Advanced Cardiac Life Support) and PALS (Paediatric Advanced Life Support) qualification is generally seen as desirable.

Barriers to the use of PSA

While PSA should not be undertaken lightly and the sedationist should adhere to guidelines and be appropriately trained, the solution is not to leave all sedation events to the specialist anaesthetist alone. While anaesthetists have unique qualifications to provide sedation, their availability is variable ⁽²⁷⁾ and is limited by commitments to the operating room ⁽²⁸⁾.

Level 1 health care facilities in South Africa don't usually employ specialists of any kind but are nevertheless responsible for administration of PSA as

determined in the L1/L2/L3 Acute Hospital Packages of care Booklet ⁽²⁹⁾, published by the Department of Health.

Despite this argument it is the author's personal experience that anaesthetists are often not very supportive of PSA performed by non-anaesthetists.

A study from Scotland confirms this opinion. A questionnaire was designed to gauge opinion of consultant anaesthetists in Scotland on the practice of conscious sedation by dentists. Of the 366 questionnaires sent, 235 were returned and valid. In general, those questioned felt that the provision of sedation in a hospital setting was more appropriate than in general dental practice. While a majority (65%) thought that it was unrealistic for anaesthetists to provide all sedation for dental treatment, 63% of the questioned anaesthetists also disagreed with current dental sedation practice with the dentist being the operator and sedationist at the same time ⁽³⁰⁾.

Models of PSA administration

To provide a solution for this dilemma more and more sedation services are relying on nursing staff to provide sedation for certain procedures.

Citation	Design	PSA Drugs used	Results	Other findings
Bassett K, et al. Can J Ophthalmol. 2007 ⁽³¹⁾	Prospective comparative case study of 105 patients received PSA for cataract surgery by nurse practitioner compared with 106 patients managed by anaesthetists	Topical analgesia +/- oral or IV midazolam, iv fentanyl	Similar efficacy and safety in both groups; no statistical difference; No adverse events relating to sedation	On patient satisfaction questionnaire, patients report "more comfort" and "faster recovery" in nurse group

Sury MRJ , et al. The Lancet 1999 ⁽³²⁾	Retrospective case analysis of 1155 sedation during 30 months	Oral drug regimen according to fixed dose-weight protocol: chloral hydrate; temazepam; droperidol; and combinations of above	Success in 97% (chloral hydrate group) and 92% (temazepam/ droperidol group). Seven minor incidents, none of which required admission	
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PSA administered by non-specialists in the ED

PSA administered in an emergency department setting requires a different set of skills due to greater variability of presenting patients and pathologies. Drugs and dosages have to be adjusted and titrated to suit individual patients' needs. Also, patients are often not fasted and sometimes intoxicated, so that airway and monitoring skills have even greater priority than in the setting of elective procedures like cataract surgery or sedation for MRIs as described above.

ED procedures are often very painful so patients are more likely to require deep sedation with its associated risk of respiratory depression, loss of airway and hypoxia.

While a number of studies have examined the skills of dedicated Emergency Physicians in terms of procedural sedation and analgesia, there is very little literature on the safety of procedural sedation administered by family physicians. At least in South Africa (and many rural settings around the world) the family physician is often responsible for provision of care in the emergency department of the District Hospitals and Community Health Centres.

The author found only one study from a rural hospital in Canada which described use of potent pharmacological agents for procedural sedation at the hands of the medical officers and family physicians staffing the ED of this hospital ⁽³³⁾. Equally, no articles were found regarding the use of procedural sedation for dilatation and curettage for patients with incomplete abortions.

This research is examining the outcome of PSA administered by Medical Officers (MO) in a district hospital in the Western Cape.

Cost of PSA versus GA

Literature on cost analysis was in general scarce. The studies that were done incorporated small patient numbers and were difficult to compare because they used different costing models.

One study evaluated 226 patients below 18 years of age who underwent 296 endoscopic procedures. The group was randomized into an intravenous sedation arm and a GA arm. Efficacy, safety, and cost in both arms were compared. While efficacy and safety was equally satisfactory in both groups, the conscious sedation group was on average charged at \$768.52, less than half that of the GA group at \$ 1965.42 ⁽³⁴⁾.

While this agrees with intuitive thinking and many articles mentioning cost containment as one of the advantages of PSA without necessarily quoting studies ⁽³⁾, an interesting American cost comparison was published in 2001, analyzing cost for GA and PSA in 22 children, having dental treatment. In this study healthy children between 2 and 5 years received GA for dental treatment. The cost for conscious sedation for the same child was then estimated, using a costing model that included societal costs, such as estimated loss of income for the parent accompanying the child. Costs were estimated to be greater in the PSA group since some children would not complete treatment under sedation and would have to return for a second appointment for dental treatment under GA ⁽³⁵⁾.

While this article is interesting the author believes the South African public health perspective might differ from the American view, even if societal costs are accounted for in so far as most public health patients are either

unemployed or are in low income employment so that the impact of societal costs will be less than estimated in America.

Also, D&C in adults differs from dental treatment in children in that completion of almost 100% of procedures would be expected.

No articles were found comparing the cost of dilatation and curettage (D&C) under general anaesthesia (GA) to procedural sedation and analgesia (PSA).

Research questions

- 1) What were the outcomes of patients who had PSA at False Bay Hospital between March 2007 and August 2009 in terms of efficacy, adverse effects and patient satisfaction ¹
- 2) What is the cost of PSA versus GA in patients that have undergone D&C for incomplete abortion at False Bay Hospital between March 2007 and September 2009 ² ?

Setting

False Bay Hospital is situated in Fish Hoek in the southern suburbs of the Cape Town Metro Health District. It is a District Hospital with capacity of 75 inpatient beds. It has two operating theatres, an OPD and a Casualty department with an annual headcount of about 14000 patients.

The Casualty department, at the time the study was conducted, was mainly staffed by medical officers, with post-graduation working experience between 5 and 12 years.

One medical officer and three nursing staff usually staff each shift with an option of calling in additional members of staff should this be required.

None of the doctors working in the ED had any formal emergency medicine or anaesthetic training at the time. All sedation providers had attended the ACLS and PALS (or equivalent) courses.

¹ Patient satisfaction questionnaire was not conducted retrospectively because of predicted poor returns.

² Cost comparison between General Anaesthesia and PSA was not undertaken

Due to lack of trained staff the hospital had no PSA service prior to commencement of the study. Procedures in the ED were either conducted without PSA or referred to a secondary hospital.

Dilatation and Curettage of RPOC were only undertaken on selected days when a local General Practitioner (GP) with a diploma in anaesthetics (DA) was available. Due to other commitments his attendances were irregular and not always predictable. On days when the GP was unavailable, patients who required a D&C were referred to the secondary hospital.

The author attended a two year diploma course in conscious sedation at UWC and subsequently provided in-house training of interested medical and nursing staff.

Subsequently a PSA service was developed at False Bay Hospital, beginning from March 2007.

All required equipment was available in the ED of the hospital.

After consultation with theatre and ED staff it was decided to conduct D&Cs for RPOC in the hospital's operating theatre (OT). This was a logistic decision, to avoid blockade of the ED. It was also expected that sedation for the D&Cs would need to be deeper than for standard emergency procedures, since a D&C is a longer procedure with a varying pain stimulus. As such, the patient would benefit from better staffing and monitoring facilities of the OT compared to the ED.

Standard guidelines for procedural sedation ⁽²⁰⁾ were followed with selection of appropriate drugs and dosages being left to the discretion of the trained sedation provider.

A logbook was kept by the author of all sedations conducted by herself or under her supervision during that time.

Aims

- 1) To determine safety, efficacy and patient satisfaction³ of procedural sedation and analgesia (PSA) in a South African district hospital staffed by non-specialists
- 2) To evaluate cost of PSA versus GA in patients who received PSA for D&C at False Bay Hospital between March 2007 and August 2009⁴.

Objectives

1. To retrospectively describe PSA as performed for emergency procedures in the ED and for D&Cs in the OT.
2. To report success of sedation and analgesia.
3. To report adverse events.
4. To report time to recovery.
5. To compare costs of PSA versus GA for the subgroup of patients that had a D&C.

Design

This study is a retrospective, descriptive series of a consecutive sample of ED patients receiving PSA.

Methods

All patients that presented to the ED of False Bay Hospital, a level one hospital in the Southern suburbs of the Cape Town Metro health district, between March 1 2007 and August 30, 2009, requiring PSA will be retrospectively evaluated.

Sample Size

³ See above, patient satisfaction questionnaire not conducted.

⁴ See above, cost comparison not done

The sample consisted of 161 patients, of which 133 received PSA in the ED.

A further 28 patients attended with incomplete abortions and had a dilatation and curettage (D&C) for retained products of conception (RPOC) in the OT. These 28 patients differed in their make up in that they were treated like elective cases, as opposed to the emergency cases treated in the ED. The patients suffering from miscarriages were fasted and their procedure was performed in the OT instead of ED.

Patient selection

Patients that received medications for the purpose of procedural sedation and analgesia, either orally, inhalational or intravenously will be included. Female patients that suffered an abortion and were treated in the OT of the same hospital with a D&C under PSA for RPOC will also be included.

Patients who received any drugs used for PSA for endotracheal intubation, seizure control, and analgesia without associated procedure were not included in the study.

The treating medical officer in the Casualty department was responsible for selection of patients that were deemed suitable for PSA at a level 1 facility, as well as choice of agents and concentrations used for PSA.

Patients selected for PSA at False Bay Hospital were generally “healthy”, meaning ASA (American Society of Anaesthetists classification) 1 or 2, or stable ASA 3 patients, free of psychiatric disease.

The ASA physical status classification system is a system that assesses a patient’s fitness for surgery. It classifies patients from one to six with the following meaning:

1=A normal healthy patient; 2=A patient with mild systemic disease; 3=A patient with severe systemic disease that limits function, but is not incapacitating; 4=A patient with severe systemic disease that is a constant threat to life; 5=A moribund patient who is not expected to survive without the operation; 6=A declared brain-dead patient whose organs are being removed for donor purposes.

Fasting status and intoxication with alcohol was evaluated and decision to proceed or defer procedure was made on a case to case basis by the responsible MO.

Patients with a viable pregnancy in need of PSA were referred to a level 2 hospital. A pre-sedation history and examination was conducted on all patients by the medical officer in the ED to determine general health and exclude allergies to PSA medications. The examination included evaluation of airway. Patients with airway problem or health problems that were found unsuitable for PSA in the described setting were referred to a level 2 hospital for treatment. Blood pressure, heart rate, temperature and O2 Saturation were performed as routine pre sedation assessment and patients were monitored throughout the procedure.

Medication

PSA medication used, included oral and intravenous (iv) midazolam, iv-ketamine, iv- morphine, iv-propofol and inhaled nitrous oxide in individually titrated dosages and combinations of above.

Consent

Informed consent was obtained for the purpose of PSA and procedure. In similar studies ^(17, 33), consent was waived for actual data review, and the author assumes that the same applies here. All data will be used without identifying patient details.

Monitoring of patients

All findings were recorded in the patients' record and in the case of the D&C patients, in a standardized anaesthetic form (*appendix1*).

During PSA, patients were monitored either by the sedation provider or, in the case of sedation provider and operator being the same person by a trained nursing sister.

Heart rate and oxygen saturation was routinely monitored in all patients. Verbal contact was maintained throughout the procedure. All findings were recorded in the patient folder.

During all D&Cs there were at least two doctors present and ECG was monitored in addition to HR, blood pressure (BP) and oxygen saturation.

Patient demographics (sex, age, ASA classification, fasting status, level of intoxication), PSA medications used, any adverse events, outcomes, rescue manoeuvres and discharge times were recorded for each patient in a standardized logbook which will be expanded and used as the data capture sheet (*appendix 2*).

Discharge of patients

Following the procedure, patients were monitored in the short stay ward until they were considered ready for discharge by the attending nursing sister and/ or Casualty MO.

Patients were considered ready for discharge, once they were:

- 1) alert/oriented to time/place/person, and conversant with clear articulation (age appropriate);
- 2) patient's cardiovascular and respiratory status were assessed to be stable and within presedation levels;
- 3) patient was able to move and coordinate all muscle groups to the same extent as prior to sedation;
- 4) patient or family (in case of paediatric patients) could verbalize post-sedation/discharge instructions;

Above described discharge criteria correlate with an **Aldrete score of 9/10**. The Aldrete score is a post anaesthetic scoring system evaluating readiness of patient for discharge.

Data collection

The author, to her knowledge, was involved in the care of all patients receiving PSA at False Bay Hospital, either as sedation provider, operator or training staff. The logbook was a requirement for the “Conscious sedation course” at UWC that the author attended. At the time the study was not planned.

It is planned to review all ED records of attendances that occurred in the stipulated time frame to ensure that no PSA event is missed. A review of patient records, anaesthetic sheets as applicable and nursing notes of the patients that received PSA in the stipulated time frame is intended. Additionally, review of records of morbidity and mortality (M&M) meetings and review of complaints that occurred from March 2007 to now is planned to identify adverse events that were not recorded in the patient records or occurred after discharge.

Presentation of results

Clinical and demographic data will be presented as means (SDs), medians, ranges, and proportions. Success of sedation and incidence of adverse effects will be presented as proportions.

Classification of adverse effects

Adverse events were categorized as follows: 1) apnoea- no respiratory effort for >20sec; 2) desaturation-O₂ saturation < 93%; 3) airway manoeuvre required (bag/valve ventilation) 4) bradycardia- HR<50 beats; 5) inadequate sedation+/- cancellation of procedure due to failure of PSA; 6) vomiting/ nausea; 7) hallucinations;

For each PSA regimen used, comparison will be made between those patients who experienced adverse effects and those patients who did not.

Ethical consideration

Record reviews risk contravening patient confidentiality. However, in this situation, the researcher was involved in the care of the patients described, so confidentiality will not be broken as far as the record review goes. No identifying details will be disclosed so patients will remain anonymous.

The use of the hospital's name could result in damaging publicity should part of this study be published.

Consent for review of records and use of the hospital name was obtained from the senior medical superintendent of False Bay Hospital, who is also one of the research supervisors.

In similar studies from overseas ^(17,33) the Ethics committee ruled that individual patient consent for review of patient records was not required and the author therefore assumes that the same applies here.

All patients were consented for the sedation and the procedure.

The number of patients is moderate and from one District Hospital only. However, the author believes that the clinical setting of this hospital is comparable to other Level 1 Health Care Facilities in the Western Cape and findings can probably be generalized to District Hospitals in the Metro District.

While drug regimens used were not standardized, all patients were treated according to PSA guidelines. ⁽²³⁻²⁵⁾

Bias

The author was involved in the medical care of all examined patients and in data collection. This is a source for bias as she might prefer positive results. All original patient records are accessible for perusal.

Other recorded outcome measures were more objective, like the recording of vital times and discharge times which was done mostly by nursing staff, minimizing the potential for bias.

The additional review of M&M records and patient complaints might not guarantee a completely unbiased view, but will add different perspectives others than the author's.

References

- (1) Windle M. *Medscape:Procedural Sedation*. Updated:2010 Sep 14. Cited: 2011, Jan 12 . Available from: <http://emedicine.medscape.com/article/109695-overview>.
- (2) Wood J. *Procedural Sedation for Cardioversion*. Updated: 20006, Oct 20. Cited: 2011, Jan 12. Available from:<http://www.bestbets.org/bets/bet.php?id=977>.
- (3) Grobler S, Potgieter A. *Office based surgery-why is it important*. CME 2009; 27(9):394-96
- (4) Bordo D, Chan SB, Shin P, West J. *Patient Satisfaction and Return to Daily Activities Using Etomidate Procedural Sedation for Orthopedic Injuries*. *Emerg Med*. 2008; 9(2): 86–90.
- (5) Stein K. *Emergency Medicine Emergency Department Protocols*. PPM. 2001;1(5):1-4. Available from: <http://www.practicalpainmanagement.com/resources/emergency-medicine-emergency-department-protocols?page=0,3>
- (6) Sergey M, Khan NGA. *Problems and barriers of pain management in the emergency department: Are we ever going to get better?* *Journal of Pain Research* .2009;2(1):5–11
- (7) Putinati S, Ballerin L, Corbetta L, Trevisani L, Potena A. *Patient Satisfaction With Conscious Sedation for Bronchoscopy*. *CHEST* 1999;115 (5): 1437-1440
- (8) MacLean S, Obispo J, Young KD. *Pediatr Emerg Care: The gap between pediatric emergency department procedural pain management treatments available and actual practice* 2007;23(2):87-93.
- (9) Stinson J, Toomey B, Stevens B, et al. *Review of systematic reviews on acute procedural pain in children in the hospital setting*. *Pain Res Manag*. 2008;13(1): 51-57
- (10) Grunau RE, Holsti L, Peters JW. *Long-term consequences of pain in human neonates*. *Semin Fetal Neonatal Med*. 2006;11(1):268-75

- (11) Walc GA, Cassidy RC, Schechter NL. Pain, Hurt and Harm: The Ethics of pain control in infants and children. *The New Eng Journ of Med.* 1994;331(8): 541-544.
- (12) Anand KJ, Aranda JV, Berde CB. Summary proceedings from the neonatal pain-control group. *Pediatrics* 2006;117(1) :9-22.
- (13) Wilson S. A survey of the American Academy of Pediatric Dentistry membership: nitrous oxide and sedation. *Pediatr Dent* 1996;18:287–93.[Medline]
- (14) Rohlfing GK, Dilley DC, Lucas WJ, Vann WF The effect of supplemental oxygen on apnea and oxygen saturation during pediatric conscious sedation *Jr.Pediatr Dent* 1998;12:228–32
- (15) Moore PA, Mickey EA, Hargreaves JA, Needleman HL. Sedation in pediatric dentistry: a practical assesment procedure. *JADA* 1984;109:564–9.
- (16) Anderson JA, Vann WF Jr. Respiratory monitoring during pediatric sedation: pulse oximetry and capnography. *Pediatr Dent* 1988;10:94–101.[Medline]
- (17) Pitetti RD, Singh S, Pierce MC. Safe and efficacious use of procedural sedation and analgesia by nonanesthesiologists in a pediatric emergency department. *Arch Pediatr Adolesc Med.* 2003;157(11):1090-6.
- (18) Roback MG, Wathen JE, Bajaj L, et al. Adverse Events Associated with Procedural Sedation and Analgesia in a Pediatric Emergency Department:A Comparison of Common Parenteral Drugs. *Acad Emerg Med* 2005;12(6):508-13
- (19) Pena BM, Krauss B. Adverse events of procedural sedation and analgesia in a paediatric emergency department. *Ann Emerg Med* 1999;34(4):483-9
- (20) Cote CJ, Notterman DA , Karl HW, Weinberg JA, McCloskey C. Adverse Sedation Events in Pediatrics: A Critical Incident Analysis of Contributing Factors. *Pediatrics.*2000;105(4):805-814

- (21) National patient safety agency. *Reducing risk of midazolam overdose in adults*. NHS, 09 December 2008
- (22) Green SM, Roback MG, Krauss B, Et al. *Predictors of airway and respiratory adverse events with ketamine sedation in the emergency department: an individual-patient data meta-analysis of 8,282 children*. *Emergency Department Ketamine Meta-Analysis Study Group*. *Ann Emerg Med*. 2009; 54(2):158-68.
- (23) American Society of Anaesthesiologists *Practice guidelines for sedation and analgesia by non-anaesthesiologists*. *Anesthesiology*. 2002;96:1004-17
- (24) American College of Emergency Physicians. *Clinical Policy: procedural sedation and analgesia in the emergency department*. *Ann Emerg Med* 2005; 45:177-96
- (25) American Academy of Pediatrics Committee on Drugs. *Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures*. *Pediatrics*. 2002;110:836-38
- (26) Hodkinson, PW, James FM, Wallis, LA. *ED procedural sedation practice in Cape Town, South Africa*, *Int J Emerg Med*. 2009;2(2):91-97
- (27). Drummond AJ. *Working group on anesthesia in the emergency department*. *J Emerg Med* 1995;13:279–81
- (28) Holzman RS, Cullen DJ, Eichhorn JH, Philip JH. *The Risk Management Committee of the Department of Anesthesia of Harvard Medical School. Guidelines for sedation by non-anesthesiologists during diagnostic and therapeutic procedures*. *J Clin Anesth*. 1994;6:265–76
- (29) Department of Health. *L1/L2/L3 Acute Hospital Packages of Care*. August 2009. Department of Health, Provincial Government of the Western Cape, August 2009.
- (30) Shearer J, Wilson KE, Girdler NM. *A survey of the opinions of consultant anaesthetists in Scotland of sedation carried out by dentists*. *Br Dent J*. 2004; 24;196(2):93-8
- (31) Bassett K, Smith SW, Cardiff K, Bergman K, Aghajanian J, Somogyi E. *Nurse anaesthetic care during cataract surgery: a comparative quality assurance study*. *Can J Ophthalmol*. 2007;42(5):689-94
- (32) Sury MRJ, Hatch DJ, Deeley T, Dicks-Mireaux C, Chong WK. *Development of a nurse-led sedation service for paediatric magnetic resonance imaging*. *The Lancet*. . 1999; 353 (9):1667 – 1671.

(33) Mensour M, Pineau R, Sahai V, Michaud. *Emergency department procedural sedation and analgesia: A Canadian Community Effectiveness and Safety Study (ACCESS)*. *CJEM* 2006;8(2):94-99

(34) Squires RH, Morriss F, Schluterman S, Drews B, Galyen L, Brown KO. *Efficacy, safety, and cost of intravenous sedation versus general anaesthesia in children undergoing endoscopic procedures*. *Gastrointest Endosc*. 1995;41(2):99-104

(35) Lee JL, Vann WF, Roberts MW. *A Cost Analysis of Treating Pediatric Dental Patients Using General Anesthesia Versus Conscious Sedation*. *Pediatr Dent*. 2000;22(1):27-32

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Part B-Literature review

Objectives of literature review and search strategy

A literature search to explore availability, efficiency and outcomes of procedural sedation and analgesia (PSA) in various clinical settings was conducted using “Pubmed” and “Google scholar” in search for English language articles between 1990 and April 2010. Combinations of the key words “conscious sedation”, “moderate sedation”, “deep sedation”, “procedural sedation”, “conscious sedation versus general anaesthesia”, “procedural sedation versus general anaesthesia”, “moderate sedation versus general anaesthesia”, “deep sedation versus general anaesthesia”, “cost”, “cost analysis”, “cost comparison”, “economy”, “incomplete abortion”, “missed abortion”, “miscarriage” “Ketamine”, “Midazolam”, “Opioids”, “Propofol”, “Ketafol”, “day case surgery”, “efficacy”, “safety”, “adverse events”, “side-effects”, “complication”, “morbidity”, “mortality”, “analgesia”, “sedation”, “emergency department”, “emergency department analgesia”, “interventional pain management”, “dilatation and curettage”, “surgical management of missed abortion”, “anaesthetic management of missed abortion”, “South Africa” and “family physician” were used.

Lack of analgesia in the Emergency Room setting

The ability to provide safe and effective sedation and analgesia is an important skill for physicians involved in emergency care. Patients are prone to anxiety in the acute setting and benefit greatly from sedation and analgesia. Despite this, it is often underused due to misconceptions and unfamiliarity with the drugs or the procedure.

Table 1: Oligoanalgesia in Emergency Departments

Author	Year	Design	Findings	Comment
Wilson and Pendleton ⁽⁹⁾	1989	Retrospective case review	Review of 198 patient charts of patients attending ED for painful conditions; 56% of patients received no analgesia while awaiting treatment. They waited over one (69%) or two (42%) hours. One third received sub-optimal	Small number of study participants.

			analgesia	
Lewis et al ⁽¹⁰⁾	1994	Retrospective study	401 patients in 8 EDs with acute bone fractures. Only 121 patients (30%) received analgesia	
O'Donnell et al ⁽¹¹⁾	2002	Retrospective case review	172 children with fractures. Only 84 (48.8%) received analgesia	Retrospective study; small numbers; patients presented with single pathology
Rawlins et al ⁽¹²⁾	2007	Retrospective case review	208 children with burns attending ED. Average age 5 yrs; only 13% received analgesia	
MacLean et al ⁽¹³⁾	2007	Retrospective case review	1700 procedures in a paediatric ED. No analgesia given for nasogastric (NGT) insertion, catheterization, iv puncture. Most I&D of abscesses done without analgesia; 71% of LPs in children under 4 months were done without analgesia	Large numbers of study participants; study relevant to research topic as procedural sedation was examined; retrospective study; indication of analgesia for NGT insertion etc is questionable

All too often physical restraint of children and adults is still seen and considered an appropriate form of immobilization for painful or anxiety-provoking procedures.

Effects of oligoanalgesia

Studies have shown that as a result of poor (procedural) analgesia, children become more anxious for further procedures and sensitized to pain in a way that decreases their pain threshold in later life ⁽¹⁴⁾. Stress associated with painful procedures can influence physiological, social and cognitive outcome⁽¹⁵⁾. Studies have concluded that procedural pain and distress, can endure in memory, resulting in disturbances of feeding, sleeping, and the stability of the state of arousal. It is known today that early experiences of pain may produce permanent structural and functional reorganization of developing nociceptive neural pathways, which in turn affects future

experiences of pain ⁽¹⁶⁾ and have emotional and psychological implications for children and families ⁽¹⁷⁾.

It is inhumane to allow any individual to suffer pain unnecessarily, when most emergency departments (ED) have the equipment and drugs to provide safe and appropriate analgesia to their patients.

Adverse effects of PSA

While provision of analgesia is important in all patients with painful conditions, this applies even more in patients undergoing painful or anxiety-provoking procedures.

However, the use of PSA does carry some inherent risks. Nausea and vomiting are not uncommon with sedation agents such as Nitrous Oxide ⁽¹⁷⁾ or Ketamine. The most serious adverse outcome of any form of paediatric (and adult) sedation is respiratory compromise with subsequent hypoxaemia and its related consequences ⁽¹⁸⁻²⁰⁾

Medical statistics differ with regards to numbers of adverse effects (AE) with conscious sedation, depending on what drugs are used and what is classified as an adverse effect (*table 2*).

Table 2: Adverse events of PSA

Citation	Design	PSA Drugs used	Results	Other findings/ Limitations
Pitetti RD et al, Arch Pediatr Adolesc Med. 2003 (21)	Prospective descriptive study of 1244 PSA events in 1215 children and young adults between 2 months and 19.4 years	IV fentanyl/ midazolam in (n=734) IV Ketamine midazolam, atropine (n=293) IM ketamine, midazolam, atropine (n=82) No non-parenteral	Successful PSA in 1177 of 1194 PSA events (98%). 207 of 1161 (17.8%) adverse events, of which 93% (193 subjects) had hypoxia (Sats < 93%), treated with oral airways, reversal agents, bag-mask ventilation, followed by vomiting in 6.2% (13 patients)	No serious adverse effects, No mortality, Large number of study participants; prospective study; Follow up (telephonically) arranged; good study, relevant to topic; children only, no other limitations

		sedation		
Mark G, Roback, al; Acad Emerg Med 2005 (22)	A retrospective comparative analysis of 2500 ED patients age 19 days to 32 years. Comparison of common parenteral drugs	Ketamine (n=1492); Ketamine/ Midazoloam (n=299) Midazolam / Fentanyl (n=336); Midazolam (n=260) Others (n=113) IV (n=2279); IM (n=221) No non-parental sedation	458 adverse events in 426 patients (17%); of these 201 (44%) with respiratory adverse event; 175 (38%) with vomiting Midazolam/ fentanyl group associated with increased risk of resp. events; Ketamine associated with vomiting. No Mortality	Comparative study; Well designed; Sufficiently large number of trial participants; Adults and paediatric patients included
Pena BM, et al. Ann Emerg Med.1999 (23)	Prospective descriptive study of 1180 ED patients, under 21 years, receiving PSA	Parenteral and non-parenteral sedation for painful procedures and imaging	27 of 1180 (2.3%) patients experienced adverse events, 16 of which had respiratory adverse event , the rest vomiting. Hypoxia defined as Sats< 90%	No serious complications. Lower number of side effects due to inclusion of non parenteral sedation and less strict definition of hypoxia;
Cote CJ, et al. Pediatrics; 2000 Apr. 105(4): 805-814 (24)	Critical Incidence Analysis of 118 adverse sedation events collected from various national (USA) sources.	Variety of PSA medications	95 incidences with consensus agreement: 51 deaths, 9 neurol. injury, 21 prolonged hospitalization; 14 no harm;	Interesting design; Analysis of adverse events only; Adverse outcomes (permanent neurol. Injury or death) associated with: non-hospital based facility, inadequate monitoring and presedation evaluation

National patient safety agency, NHS, 09 December 2008 ⁽²⁵⁾	Critical Incidence Analysis of 498 adverse sedation events (UK) involving iv midazolam;	Iv midazolam	3 deaths; 48 patients sustained moderate harm; 447 patients with no or low harm	Medication errors (dosages) due to problematic packaging and lack of staff training were main contributors to poor outcome.
Green SM, et al. Ann Emerg Med. 2009 Aug;54 ⁽²⁶⁾	Patient data meta analysis of 8282 paediatric ketamine sedations; Multiple regression analysis to determine clinical predictors of airway and respiratory adverse events	Ketamine sedation	Airway and respiratory adverse event rate of 3.9% Predictors of adverse respiratory events: -Age < 2yrs or >13 yrs; -High iv dosing of ketamine (>2.5mg/kg initially or > 5mg/kg total dose); -Co-administered Benzodiazepines or anticholinergics -Underlying physical illness; -Oropharyngeal procedures; -IV vs IM route	Large number of patients from 32 ED departments; Well designed observational study However as observational study not ideally designed to draw conclusions about treatment

PSA Guidelines

In order to keep adverse effects of PSA to a minimum, many specialty societies and regulatory bodies have published guidelines for procedural sedation and analgesia, each designed to address their specific priorities. Factors like medication errors or other human mistakes can probably never be fully avoided. However, most issues associated with adverse outcomes have been addressed in all of the well-known guidelines. All known guidelines emphasize importance of presedation patient assessment, monitoring of the patient, appropriate skills of sedationist as well as facilities and minimum

equipment requirements. The most widely circulated guidelines were produced by:

- 4) The American Society of Anaesthesiologists ⁽²⁷⁾,
- 5) The American College of Emergency Physicians ⁽²⁸⁾ and
- 6) The American Academy of Paediatrics ⁽²⁹⁾.

While South Africa has its own set of guidelines, they are not regularly utilised. This was demonstrated by a recent study of PSA in EDs of the Western Cape ⁽³⁰⁾.

The practice guidelines for sedation and analgesia by non-anaesthetists ⁽²⁷⁾ recommend that “individuals responsible for patients receiving sedation-analgesia should understand the pharmacology of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines. Individuals monitoring patients receiving sedation/analgesia should be able to recognize the associated complications. At least one individual capable of establishing a patent airway and positive pressure ventilation should be present whenever sedation analgesia is administered.”

While not (yet) mandatory for the medical or dental practitioner administering procedural sedation, an ACLS and PALS qualification is seen as desirable. This point was made on a number of occasions during the lectures that formed part of the conscious sedation diploma course at the University of Western Cape. ACLS or PALS certificate enables the practitioner to rescue patients with airway problems, which are the most hazardous adverse effects resulting from PSA ⁽¹⁸⁻²⁰⁾.

Barriers to the use of PSA

While PSA should not be undertaken lightly and the sedationist should adhere to guidelines and be appropriately trained, the solution is not to leave all sedation events to the specialist anaesthetist alone. While anaesthetists have

unique qualifications to provide sedation, their availability is variable ⁽³¹⁾ and is limited by commitments to the operating room ⁽³²⁾.

Furthermore level 1 health care facilities in South Africa don't usually employ specialists of any kind but are responsible for administration of PSA as determined in the L1/L2/L3 Acute Hospital Packages of care Booklet ⁽³³⁾, published by the Department of Health.

Nevertheless PSA administration by non-anaesthetists is often a contentious subject, as the following study highlights.

In a study from Scotland a questionnaire was designed to gauge opinion of consultant anaesthetists in Scotland on the practice of conscious sedation by dentists. Of the 366 questionnaires sent, 235 were returned and valid. In general, those questioned felt that the provision of sedation in a hospital setting was more appropriate than in general dental practice. While a majority (65%) thought that it was unrealistic for anaesthetists to provide all sedation for dental treatment, 63% of the questioned anaesthetists also disagreed with current dental sedation practice with the dentist being the operator and sedationist at the same time ⁽³⁴⁾.

Models of PSA administration

To provide a solution for this dilemma more and more sedation services are relying on nursing staff to provide sedation for certain procedures.

Table 3: Outcomes of PSA administered by nurses

Citation	Design	PSA Drugs used	Results	Limitations
Bassett K, et al. Can J Ophthal mol. 2007 ⁽³⁵⁾	Prospective case study of 105 patients received PSA for cataract surgery by nurse practitioner compared with 106 patients managed by anaesthetists	Topical analgesia +/- oral or IV midazolam, iv fentanyl	Similar efficacy and safety in both groups; no statistical difference; No adverse events relating to sedation On patient satisfaction questionnaire, patients report “more comfort” and “faster recovery” in nurse group;	Study not blinded and not randomized; poor design; however one of few studies to take patient satisfaction into account
Sury MRJ, et al. The Lancet 1999 ⁽³⁶⁾	Retrospective case analysis of 1155 sedation for imaging during 30 months	Oral drug regimen according to fixed dose-weight protocol: chloral hydrate; temazepam; droperidol; and combinations of above	Success in 97% (chloral hydrate group) and 92% (temazepam/droperidol group). Seven minor incidents, none of which required admission	Low complication rate b/o non-parenteral low dose drug regimen for elective, painless procedure

PSA administered by non-specialists in the ED

PSA administered in an emergency department setting requires a unique set of skills. The Casualty patient requiring PSA often suffers from very painful conditions and additionally is rarely fasted and frequently intoxicated. This predisposes patients to over-sedation and airway problem when compared with elective patients receiving sedation for less painful procedures like cataract surgery or imaging as discussed above (*table 3*). Drugs and dosages have to be adjusted and titrated to suit individual patients' needs. Airway and monitoring skills have even greater priority than in the setting of elective procedures as described above.

While a number of studies have examined the skills of dedicated Emergency Physicians in terms of procedural sedation and analgesia, there is very little literature on the safety of procedural sedation administered by family physicians. At least in South Africa (and many rural settings around the world) the medical officer (MO) or family physician is often responsible for provision of care in the emergency department of the District Hospitals and Community Health Centres.

Few studies report outcomes of PSA at the hands of the medical officers and family physicians ⁽³⁷⁾ or the use of procedural sedation for dilatation and curettage for patients with incomplete abortions.

There is consequently a gap in knowledge as to the outcomes of PSA delivered by general medical officers and Family Physicians. This research, by evaluating the outcome of PSA administered by Medical Officers (MO) in a district hospital in the Western Cape, aims to contribute towards closing this gap.

PSA and fasting

One of the advantages of PSA over General Anaesthesia (GA) is that it allows preservation of patients' airway reflexes. Fasting, which is ideally required before deep sedation and GA, where airway reflexes are not preserved, is not always feasible in emergencies. Some studies and guidelines have examined and commented on the need for pre-procedure fasting to minimise aspiration among patients undergoing procedural sedation and analgesia for emergency procedures ⁽³⁸⁾. The American College of Emergency Physicians Clinical Policies Subcommittee on Procedural Sedation and Analgesia issued a recommendation based on 'preliminary, inconclusive or conflicting evidence, or on panel consensus'. The recommendation states: "recent food intake is not a contraindication for administering procedural sedation and analgesia" ⁽²⁸⁾.

A study conducted by Bell in an emergency department in Australia compared patients who last ate or drank more than 6 and 2 h from induction, respectively, with those who last ate or drank within 6 and 2 h. There were no

cases of aspiration in either group. Out of 118 patients who fasted, 1 (0.8%) vomited, as did one of 282 patients (0.4%) who did not fast⁽³⁹⁾.

A further systematic review of the literature conducted by Thorpe et al with the aim of evaluating the evidence for risk of pulmonary aspiration during emergency procedural sedation in adults found only one reported case of pulmonary aspiration during emergency procedural sedation, among 4657 adult cases and 17 672 paediatric cases reviewed⁽⁴⁰⁾.

Routine fasting has not proven to be beneficial prior to procedural sedation in the majority of patients at the Emergency Department.

However, patients undergoing sedation or analgesia for elective procedures should be fasted to allow for gastric emptying before the procedure, in concurrence with the ASA Guidelines for pre-operative fasting. The guidelines recommend fasting period of 2 hours for clear liquids, 4 hours for breast-milk and 6 hours for other milk and solid food.

In this research most of the ED patients that received PSA were not fasted, while all of the elective patients, receiving PSA for D&C of retained products of conception were fasted for 6 hours as per ASA guidelines.

Commonly used PSA Drugs

The drugs that were used for PSA on the patients reviewed in this research were Ketamine, Nitrous oxide, Midazolam, Morphine, Valeron (=Tilidin hydrochloride) and Propofol. These were used either as single agents or in combination within the dosages specified in the table below.

Table 4: Commonly used PSA drugs (1,41)

Drug	Adult Dose	Onset of Action	Duration of Action	Comments
Midazolam (Versed)	0.01-0.1 mg/kg IV initially; may repeat with 25% of initial dose after 3-5 min;	1-2 min	30-60 min	Respiratory depression or hypotension may occur, esp. In combination with opioid; does not provide analgesia; action reversed by flumazenil

Morphine sulfate	Starting dose 0.1 mg/kg iv/im/sc; Maintenance 5-20 mg/ 70 kg adult; Paeds: 0.08-0.1 mg/kg before procedure	15-30 min following iv dose	2-4 hours	May cause chest wall rigidity, apnoea, respiratory depression, or hypotension due to histamine release; nausea and vomiting; action reversed by naloxone
Valoron (=Tilidine) drops (1drop= 2.5mg)	<u>Adults</u> : 20drops 3-4 times daily; Paeds: One mg/ kg per single dose should not be exceeded	45 min	3-4hrs	Similar side effect profile to morphine sulphate
Ketamine	0.2-0.75 mg/kg IV infused over 2-3 min in adults; 1-1.5 mg/kg slow IV push (not to exceed 0.5 mg/kg/min), may administer additional doses of 0.5 mg/kg IV q10-15min	1-2min	30-60 min	increases bronchial and salivary secretions; increases heart rate, blood pressure, and intracranial pressure; emergence hallucinations; pharmacologic effects NOT reversible
Propofol	Adult Monitored anaesthesia care (MAC) sedation: 0.5 mg/kg IV infused over 3-5 min initially Maintenance: 25-75 mcg/kg/min IV or incremental IV bolus doses of 10-20 mg	<1 min	3-10 min	Provides rapid onset and recovery phase, and brief duration of action; anticonvulsant properties; can rapidly cause deepening sedation; causes cardiovascular depression and hypotension
Nitrous oxide	Inhale 1:1 mixture of oxygen and nitrous oxide via handheld mask or mouthpiece Typically, patients are to maintain the seal to ensure adequate inhalation; once sedation is approached, the patient will lose seal and allow the mask/mouthpiece to fall	1-2min	Short recovery period once discontinued; 3-5 mins	Very low side effect profile. Good safety record even in small children. Can cause nausea and vomiting; PROLONGED (> 1hour) exposure causes bone marrow suppression; not usually harmful when used for PSA

Drugs like Alfentanyl and Remifentanil are not further discussed here as they were not available to level 1 district hospitals in South Africa at the time of study.

Of all above drugs, Ketamine stands out, because of its lack of a characteristic dose-response continuum by progressive titration, which is typical for other sedatives. At doses below a certain threshold, ketamine produces analgesia and sedation. However, once the critical dosage threshold of roughly 1–1.5 mg/kg IV is reached, the characteristic dissociative state abruptly appears. Because of this, the dissociative state is not consistent with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

definitions of moderate sedation, deep sedation, or general anaesthesia; therefore, ketamine must be considered from a different perspective than drugs with the classical sedation continuum ⁽¹⁾. It is because of these characteristics that Ketamine still is commonly used for PSA. The dissociative state it produces at relatively low dosages while at the same time allowing the patient to maintain protection of his airway make it a safe and efficient drug for PSA in the hand of the “Non-anaesthetist”.

All of above drugs have been evaluated in a number of trials and found to be safe, with an acceptable side effect profile for PSA.

Morphine, while still used in procedural sedation, is less popular than shorter acting opiates like Fentanyl.

In our setting the use of Morphine was dictated by availability and familiarity of all providers with the drug. The long half time of morphine can cause respiratory depression that lasts longer than the actual procedure and as such warrants close monitoring following PSA and might delay discharge time.

The table below outlines details of studies that examined safety and efficiency of above described PSA drugs.

Table 5: Evidentiary Table- PSA drugs ⁽²⁸⁾

Study	Design	Findings	Limitations	Conclusions
Chudnofsky et al ⁽⁴²⁾	Prospective, observational trial	ED study of 70 patients aged >18 yrs who received 0.07 mg/kg of IV midazolam followed by 2 mg/kg of IV ketamine for I&D (26%), fracture/joint reduction (26%), and other (8%); there were no episodes of hallucinations, delirium, or other Emergency reactions; 18 (25%) patients recalled (pleasant or unpleasant) dreaming during sedation,	No control group; lack of reliability in recognition of emergence reactions	Midazolam and ketamine in combination provide effective and safe procedural analgesia in adult ED patients
Wathen et al ⁽⁴³⁾	Double-blind, randomized, controlled study	ED study of 266 patients aged 4.5 months to 16 y to evaluate frequency and severity of adverse effects in patient receiving ketamine with or without midazolam for sedation; 129 patients received ketamine and 137 received ketamine and midazolam; similar incidence of side effects in both groups	No major limitations	Ketamine and combined ketamine and midazolam provide equally effective sedation
Dachs and Innes ⁽⁴⁴⁾	Observational study	30 children aged 18 mo to 8 y; bolus of 1.5 mg/kg produced adequate sedation in 17/18 (94%) patients	Design, small numbers	Ketamine is an effective method of PSA in children
Bassett et al ⁽⁴⁵⁾	Prospective observational study	392 patients 1-18yrs received Propofol 1mg/kg +/- additional 0.5 mg/kg + narcotic. O2 Sats maintained in 95%; partial airway obstruction in 3%, 0.08% required bag/ mask ventilation	Depth of sedation not objectively scored	Propofol is safe and effective when administered in the ED
Gall et al ⁽⁴⁶⁾	Prospective, multicentre clinical trial	Examination of frequency of adverse events in 7511 sedation events of children sedated with 50% Nitrous oxide and oxygen over a broad range of non-specialised facilities. A mean of 0.33 % (SD 0.10) children had major adverse events.	No major limitations	premixed 50 % Nitrous oxide and Oxygen is safe for procedural sedation in children

Above table shows evidence that suggests that the drugs used in this research have all previously shown to be safe.

There is little research done on the usefulness of Valeron drops for conscious sedation.

Equipment and Monitoring of patients receiving PSA

Equipment and monitoring in any medical situation is always dictated by the “worst possible case scenario”. Although rare, PSA could potentially result in respiratory arrest, cardio-pulmonary arrest or anaphylactic shock, following an allergic drug reaction.

The incidence of complications is dependent on type and dose of drugs, the procedure that is performed, experience of sedation provider and patient state of health.

As such the appropriate monitors and equipment to manage airways, allergic reactions and drug overdoses and treat respiratory and cardio-pulmonary arrest should be readily available. This includes oxygen, suction, medications, and advanced life support equipment (bag-mask ventilation device and intubation equipment)

The minimum requirements for monitoring of patients undergoing PSA are specified in all of above mentioned PSA guidelines ⁽²⁷⁻²⁹⁾. Vital signs should be obtained and monitored before, during and after procedure. Vital signs include respiratory rate, oxygen saturation, exhaled carbon dioxide, heart rate, blood pressure and cardiac rhythm monitoring via ECG. The patient’s consciousness level should be monitored by testing his ability to follow commands.

Documentation of the patient’s status before, during and after procedure is recommended.

According to a study conducted by Newman et al, the highest risk of serious adverse events following administration of PSA is within 25 minutes of the last dose of intravenous PSA medication with a median of 2 min after the final medication dosing ⁽⁴⁷⁾.

This study illustrates two things; monitoring after a procedure, especially a short procedure is important because the depressing effect of PSA drugs persist after procedure is concluded. Ideally this should be done by a dedicated and trained health care provider/ nurse.

On the other hand it shows that discharge after PSA within an hour is in many cases safe and feasible.

Further research

There is plenty of scope for future research in the field of PSA in general and in the field of PSA by non-anaesthetists in particular.

PSA using inhalational agents other than nitrous oxide is certainly a field for future research.

Research into optimal dosing strategies for ED Propofol⁽⁴⁹⁾ as well as “Ketafol” (Ketamine and Propofol combination), including variations of dosing based on patient- age, underlying illness and weight should continue. Hand in hand with introduction of Propofol into ED-PSA goes research into the impact of additional monitoring modalities on the incidence of Propofol (and PSA) related respiratory events. Of special interest would be the role of capnography in PSA in general and in Propofol PSA in particular.

Predictors of adverse events, including patient factors, like non-fasting status and mild intoxication which is commonly encountered in South Africa EDs, PSA medications uses and PSA provider factors (anaesthetist vs trained/ untrained MO/ Generalist) deserve to be examined closer.

Overall larger studies will be required to accurately predict the incidence of adverse events of PSA in the emergency department.

An interesting field, especially for family physicians would be research focusing on patient satisfaction and acceptability of PSA.

References:

- (1) Windle M. *Medscape:Procedural Sedation*. Updated:2010 Sep 14. Cited: 2011, Jan 12 . Available from: <http://emedicine.medscape.com/article/109695-overview>.
- (2) Wood J. *Procedural Sedation for Cardioversion*. Updated: 20006, Oct 20. Cited: 2011, Jan 12. Available from: <http://www.bestbets.org/bets/bet.php?id=977>.
- (3) Grobler S, Potgieter A. *Office based surgery-why is it important*. CME, 2009 ;27(9):394-96
- (4) Bordo D, Chan SB, Shin P. West J .*Patient Satisfaction and Return to Daily Activities Using Etomidate Procedural Sedation for Orthopedic Injuries*. *Emerg Med*. 2008;9(2):86–90.
- (5) Stein K. *Emergency Medicine Emergency Department Protocols*. PPM. 2001;1(5):1-4. Available from: <http://www.practicalpainmanagement.com/resources/emergency-medicine-emergency-department-protocols?page=0,3>
- (6) Sergey M, Khan NGA. *Problems and barriers of pain management in the emergency department: Are we ever going to get better?* *Journal of Pain Research* 2009;2(1):5–11
- (7) Wilson JE, Pendleton JM. *Oligoanalgesia in the emergency department*. *Am J Emerg Med*. 1989;7:620–623.
- (8) Putinati S, Ballerin L, Corbetta L, Trevisani L, Potena A. *Patient Satisfaction With Conscious Sedation for Bronchoscopy*. *CHEST* ; 1999;115(5):1437-1440
- (9) Wilson JE, Pendleton JM. *Oligoanalgesia in the emergency department*.*Am J Emerg Med*. 1989;7:620–623.
- (10). Lewis LM, Lasater LC, Brooks CB. *Are emergency physicians too stingy with analgesics?* *South Med J*. 1994;87:7–9.
- (11) O'Donnell J, Ferguson LP, Beattie TF. *Use of analgesia in a paediatric accident and emergency department following limb trauma*. *Eur J Emerg Med*. 2002;9:5–8.
- (12) Rawlins JM, Khan AA, Shenton AF, Sharpe DT. *Epidemiology and outcome analysis of 208 children with burns attending an emergency department*. *Pediatr Emerg Care*. 2007;23:289–233.

- (13) MacLean S, Obispo J, Young KD. The gap between pediatric emergency department procedural pain management treatments available and actual practice. *Pediatr Emerg Care*. 2007;23(2):87-93.
- (14) Stinson, J, Et al. Review of systematic reviews on acute procedural pain in children in the hospital setting. *Pain Res Manag*. 2008;13(1):51-57
- (15) Grunau RE, Holsti L, Peters JW. Long-term consequences of pain in human neonates. *Semin Fetal Neonatal Med*. 2006;11:268-75
- (16) Walc GA, Cassidy RC, Schechter NL. Pain, Hurt and Harm: The Ethics of pain control in infants and children. *The New Eng Journ of Med*. 1994; 25;331,(8):541-544.
- (16) Anand KJ, Aranda JV, Berde CB. Summary proceedings from the neonatal pain-control group. *Pediatrics*. 2006;117:9-22.
- (17) Wilson S. A survey of the American Academy of Pediatric Dentistry membership: nitrous oxide and sedation. *Pediatr Dent* 1996;18:287–93.[Medline]
- (18) Rohlfing GK, Dilley DC, Lucas WJ, Vann WF. The effect of supplemental oxygen on apnea and oxygen saturation during pediatric conscious sedation. *Jr.Pediatr Dent* 1998;12:228–32
- (19) Moore PA, Mickey EA, Hargreaves JA, Needleman HL. Sedation in pediatric dentistry: a practical assesment procedure. *JADA* 1984;109:564–9.
- (20) Anderson JA, Vann W. Respiratory monitoring during pediatric sedation: pulse oximetry and capnography. *Pediatr Dent* 1988;10:94–101.[Medline]
- (21) Pitetti RD, Singh S, Pierce MC. Safe and efficacious use of procedural sedation and analgesia by non-anesthesiologists in a pediatric emergency department. *Arch Pediatr Adolesc Med*. 2003;157(11):1090-6.
- (22) Roback MG, Wathen JE, Bajaj L, Bothner, JP. Adverse Events Associated with Procedural Sedation and Analgesia in a Pediatric Emergency Department:A Comparison of Common Parenteral Drugs. *Acad Emerg Med* 2005;12(6):508-13
- (23) Pena BM, Krauss B. Adverse events of procedural sedation and analgesia in a paediatric emergency department. *Ann Emerg Med*.1999;34(4):483-9
- (24) Cote CJ, Notterman DA, Karl HW, Weinberg JA, McCloskey C. Adverse Sedation Events in Pediatrics: A Critical Incident Analysis of Contributing Factors. *Pediatrics* 2000;105(4):805-814

- (25) National patient safety agency. *Reducing risk of midazolam overdose in adults*. NHS, 09 December 2008
- (26) Green SM, Roback MG, Krauss B, Brown L, McGlone RG, Agrawal D, Et al. *Predictors of airway and respiratory adverse events with ketamine sedation in the emergency department: an individual-patient data meta-analysis of 8,282 children*. *Ann Emerg Med*. 2009;54(2):158-68.
- (27) American Society of Anaesthesiologists. *Practice guidelines for sedation and analgesia by non-anaesthesiologists*. *Anesthesiology* 2002;96:1004-17
- (28) American College of Emergency Physicians. *Clinical Policy: procedural sedation and analgesia in the emergency department*. *Ann Emerg Med* 2005; 45:177-96
- (29) American Academy of Pediatrics Committee on Drugs. *Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures*. *Pediatrics* 2002; 110:836-38
- (30) Hodkinson, PW, James FM, Wallis, LA. *ED procedural sedation practice in Cape Town, South Africa*. *Int J Emerg Med*. 2009; 2(2):91-97
- (31). Drummond AJ. *Working group on anesthesia in the emergency department*. *J Emerg Med* 1995;13:279–81.
- (32) Holzman RS, Cullen DJ, Eichhorn JH, Philip JH. *Guidelines for sedation by non-anesthesiologists during diagnostic and therapeutic procedures. The Risk Management Committee of the Department of Anesthesia of Harvard Medical School*. *J Clin Anesth*. 1994;6:265–76
- (33) Department of Health. *L1/L2/L3 Acute Hospital Packages of Care*. August 2009. Department of Health, Provincial Government of the Western Cape, August 2009.
- (34) Shearer J, Wilson KE, Girdler NM. *A survey of the opinions of consultant anaesthetists in Scotland of sedation carried out by dentists*. *Br Dent J*. 2004; 24:196(2):93-8.
- (35) Bassett K, Smith SW, Cardiff K, Bergman K, Aghajanian J, Somogyi E. *Nurse anaesthetic care during cataract surgery: a comparative quality assurance study*. *Can J Ophthalmol*. 2007;42(5):689-94.
- (36) Sury MRJ, Hatch DJ, Deeley T, Dicks-Mireaux C, Chong WK. *Development of a nurse-led sedation service for paediatric magnetic resonance imaging*. *The Lancet*. 1999; 353 (9):1667 –71.

- (37) Mensour M, Pineau R, Sahai V, Michaud. *Emergency department procedural sedation and analgesia: A Canadian Community Effectiveness and Safety Study (ACCESS)*. *CJEM* 2006;8(2):94-99
- (38) Molina JA , Lobo C, Goh HK, Seow E, Heng BH. *Review of studies and guidelines on fasting and procedural sedation at the emergency department*. *Intern. Journal of Evidence-Based Healthcare*. 2010;8(2):75-78.
- (39) Bell A., Treston, G., McNabb C., Monypenny K. Cardwell R. , *Profiling adverse respiratory events and vomiting when using propofol for emergency department procedural sedation*. *Emergency Medicine Australasia* 2007; 19: 405–10.
- (40) Thorpe RJ, Benger J; *Pre-procedural fasting in emergency sedation; Emerg Med J* 2010;27:254-261
- (41) Morgan GE, Mikhail MS, Murray MJ; *Clinical Anesthesiology (4th edition)* Michael J. Murray Publisher, 2005
- (42) Chudnofsky CR, Weber JE, Stoyanoff PJ, et al. *A combination of midazolam and ketamine for procedural sedation and analgesia in adult emergency department patients*. *Acad Emerg Med*. 2000;7:228-235.
- (43). Wathen JE, Roback MG, Mackenzie T, Et al. *Does midazolam alter the clinical effects of intravenous ketamine sedation in children? A double-blind, randomized, controlled, emergency department trial*. *Ann Emerg Med*. 2000;36:579-588.
- (44). Dachs RJ, Innes GM. *Intravenous ketamine sedation of pediatric patients in the emergency department*. *Ann Emerg Med*. 1997;29:146-150.
- (45). Bassett KE, Anderson JL, Pribble CG, et al. *Propofol for procedural sedation in children in the emergency department*. *Ann Emerg Med*. 2003;10:931-37
- (46) Gall O, Annequin D, Benoit G, Van Glabek E, Vrancea F; *Adverse events of premixed nitrous oxide and oxygen for procedural sedation in children* *Lancet* 2001; 358:1514-15
- (47) *When is a patient safe for discharge after procedural sedation? The timing of adverse effect events in 1,367 pediatric procedural sedations; Newmann DH, Azer MM, Pitetti RD, Singh S; Annals of Emergency Medicine*. 2003;42(5):627-35.
- (48) Squires RH , Morriss F, Schluterman S, Drews B, Galyen L, Brown KO. *Efficacy, safety, and cost of intravenous sedation versus general anaesthesia in children undergoing endoscopic procedures*. *Gastrointest Endosc*. 1995;41(2):99-104

*(49) Milner JR, Burton JH; Clinical Practice Advisory: Emergency Department
Procedural Sedation With Propofol; Ann Emerg Med. 2007;50:182-187*

Part C- Results⁵

⁵ Article as accepted for publishing by SAMJ

Abstract

Objectives: This study aimed to research efficacy and safety of procedural sedation and analgesia (PSA) administered by medical officers (MOs), without formal anaesthetic training, in a South African district hospital. **Design:** This is a retrospective descriptive study. **Setting:** The study took place in the Emergency Department (ED) of False Bay Hospital (FBH), a level one hospital in the Southern suburbs of the Cape Town Metro health district. **Subjects:** All patients who received procedural sedation and analgesia at FBH between March 1, 2007 and August 31, 2009 were included. **Outcome measures:** Variables that were recorded in the logbook/ data extraction sheet included age, sex, physical status as determined by the American Society for anaesthetists (ASA status), procedure, fasting and intoxication status, PSA medications, adverse effects, rescue manoeuvres performed, if any, and time to discharge. Data was entered into an Excel spreadsheet and analysed. Analysis was largely descriptive and clinical and demographic data have been presented as means (SDs), medians, ranges, and proportions as appropriate. Success of sedation and incidence of adverse effects have been presented as proportions. **Results:** Of 166 patients, 140 (84.33%) showed a good level of sedation. Fourteen patients (8.43%) were inadequately sedated. Five patients were too deeply sedated (3%) but showed no signs of respiratory compromise and seven patients (4.2%) developed respiratory side effects. All respiratory complications were treated with simple airway manoeuvres. No patients required intubation or experienced respiratory problems after waking up. There was no significant difference in the risk of adverse effects between the fasted and non-fasted patient groups. Patient who were mildly intoxicated and received PSA were at a higher risk of adverse effects. Due to small numbers of subjects these findings were not statistically significant. **Conclusion:** Procedural sedation and analgesia can be administered safely by Medical Officers. Future research should expand on PSA research in this setting and focus not just on safety but also on patient satisfaction with PSA.

Introduction

Procedural sedation and analgesia is a skill commonly required when dealing with patients in the emergency department (ED). Typical procedures which can be performed under PSA in the ED or minor theatre setting are reduction of fractures and dislocations (commonly shoulder, hip, elbow, jaw) , incision and drainage of abscess (I&Ds) , laceration repair in children, foreign body (FB) removal or evacuation of retained products of conception (RPOC).

Omitting to provide sufficient analgesia is associated with a number of unwanted physiological and psychological side effects, including increased sympathetic outflow, peripheral vascular resistance, myocardial oxygen consumption, production of carbon dioxide (CO₂), hypercoagulability, decreased gastric motility, decreased immune function, and the subsequent development of chronic pain.⁽¹⁻³⁾

In the last decade a lot of research has been conducted, proving safety and efficacy of PSA when administered by emergency physicians in ED Units around the world.

There is a paucity of studies on PSA administration by non-specialists in the public health sector in South Africa.⁽⁴⁾ The majority of the population (over 80%) is serviced by the state funded public sector hospitals which are often overcrowded and under-resourced.⁽⁵⁾

According to the South African Department of Health⁽⁶⁾, it is the responsibility of the MO or family physician to care for patients in the emergency room and administer of PSA.⁽⁷⁾

The objectives of this study are to analyze safety and efficacy of PSA when provided by MOs in a South African peri-urban district hospital. Furthermore the influence of fasting- status and intoxication on sedation outcome and adverse effect rate will be examined.

Setting

False Bay Hospital is situated in Fish Hoek in the southern suburbs of the Cape Town Metro Health District.

The hospital is attended by a diverse group of patients, including patients from a very low socio-economic background, as well as a number of wealthier patients, belonging to medical aids.

It is a District Hospital with capacity of 75 inpatient beds. It has two operating theatres, an outpatient department (OPD) and a Casualty department with an annual headcount of about 14000 patients.

At the time the study was conducted, the Casualty department was staffed by medical officers, with post-graduation working experience between 5 and 12 years and no formal emergency medicine or anaesthetic training.

Due to lack of trained staff the hospital had no PSA service prior to commencement of the study. This is a situation that is mirrored in many of the smaller primary healthcare facilities in South Africa. Procedures in the ED were either conducted without PSA or referred to a secondary hospital.

Prior to 2007 dilatation and curettage (D&C) of uterus following incomplete or missed abortion were only undertaken on selected days when a local General Practitioner (GP) with a diploma in anaesthetics (DA) was available. On days when the GP was unavailable, patients who required a D&C were referred to a secondary hospital. The author attended an accredited two year diploma course in conscious sedation at the University of the Western Cape (UWC) and subsequently provided in-house training of interested medical and nursing staff.

PSA Guidelines⁽⁸⁻¹⁰⁾ were circulated to staff involved in PSA and adhered to.

Methods

Records of all patients that presented to the ED of False Bay Hospital, between March 1 2007 and August 30, 2009, requiring PSA were retrospectively evaluated, as a retrospective consecutive case series.

Patients who received medications for the purpose of procedural sedation and analgesia, either orally, inhalational or intravenously were included. Female

patients who had incomplete abortions and were treated in the minor operation theatre (OT) of the same hospital with a D&C under PSA were included.

Patients who received any of the drugs usually administered for PSA for endotracheal intubation, seizure control, and analgesia without associated procedure were not included in the study.

The treating medical officer in the Casualty department was responsible for selection of patients that were deemed suitable for PSA at a level 1 facility, as well as choice of agents used for PSA. All healthcare staff participating in PSA had in-house training in the use of relevant PSA medication and standardized guidelines⁽⁸⁻¹⁰⁾ were followed.

Drugs were used at doses suitable for PSA as opposed to anaesthetic doses. Propofol was mixed into a 1:1 solution with Ketamine and commenced at a dosage of 0.2mg/kg for each drug and then slowly titrated to desired effect in 2mls increment (1ml of the mixed solution contained 5mg of Propofol and Ketamine each).

Ketamine was used at a starting dose of 0.5mg/ kg and slowly titrated in increments of 0.2 mg/kg.

Drug choices were up to the attending MO. The author attended a “Conscious sedation diploma” course as offered by UWC and provided some of the in-house training.

All MOs administering PSA had attended ACLS, ATLS and PALS courses.

Patients selected for PSA at False Bay Hospital were generally “healthy”, meaning ASA (American Society of Anaesthetists classification) 1 or 2, or stable ASA 3 patients, free of psychiatric disease.

Fasting status and intoxication with alcohol was evaluated and decision to proceed or defer procedure was made on a case to case basis by the responsible MO. None of the patients in the Casualty group were fasted. Ten patients were mildly intoxicated but found suitable for PSA. One patient’s procedure was deferred due to the level of intoxication.

All of the patients for D&C were fasted.

Informed consent was obtained for the procedure and sedation.

Ethics approval for this study was obtained from the UCT Ethics committee.

Each procedural sedation event was recorded on a standardized Anaesthetic record sheet (appendix 1).

Variables that were recorded included age, sex, ASA status, presenting problem, fasting status, clinical impression of intoxication, PSA medications and dosages used, adverse effects, rescue manoeuvres performed, if any, time to discharge if discharged or other disposal of patient.

Patients were monitored throughout the procedure with continuous pulse oximetry and heart rate measurements, as well blood pressure measurements before commencement of procedure and at two minute intervals.

Readiness for discharge was determined in accordance with an Aldrete score of 9/10.

Adverse events were categorized as follows: 1) apnoea- no respiratory effort for >20sec; 2) desaturation-O₂ saturation < 93%; 3) airway manoeuvre required (bag/valve ventilation=BVM) 4) bradycardia- HR<50 beats; 5) inadequate sedation+/- cancellation of procedure due to failure of PSA; 6) vomiting/ nausea; 7) hallucinations.

Results

The data was entered into an Excel spreadsheet and analysed. Data analysis is largely descriptive and clinical and demographic data has been presented as means (SDs), medians, ranges, and proportions as appropriate. Success of sedation and incidence of adverse effects have been presented as proportions.

The mean age was 23 years (SD 17.98). The oldest patient was 88 years and the youngest patient was 3 months old. Table 1 describes the frequency of other demographic variables.

The intended procedures could be completed in 165 of 166 patients (99.4%). Nine patients (5.42%) experienced adverse effects, all of which were minor, with no intubation required and no long-term problems as judged by review of patient

records and review of Mortality and Morbidity (M&M) meetings for the time span concerned.

Table 2 contains the breakdown of adverse events for PSA study patients

There was no statistically significant difference between complication rate for male and female patients. ($p > 0.05$)

There was a statistical difference in the age of the patients that experienced complications versus the age of the patients that did not ($p=0.0024$). The patients that experienced side effects from their treatment were on average older with a median age of 40 years versus a median age of 22 years for the patients that did not experience side effects.

The youngest patient experiencing adverse effect was 19 years.

When analyzing the different medication groups for complications, the numbers were too low for statistical analysis. However, there was a trend for a higher complication rate with addition of Propofol and with use of multiple sedation drugs.

When analyzing adverse events in fasted, versus non-fasted, versus intoxicated patients, the numbers were too small to arrive at statistically significant conclusions, but there was a tendency for intoxicated patients to develop complications, while there was little difference in adverse effect rate (AER) between fasted and non fasted patients (Table 3)

One hundred and forty three patients were discharged following their procedure. The remaining 23 patients required admission or referral for definite treatment. None of the admissions or referrals was related to PSA. The mean discharge time was 73 minutes (SD 60.33%) with shortest discharge time of 10 minutes and longest discharge time of 222 minutes

Table 1: Demographic details of PSA patients

Variable	No (%) of patients
<u>Gender</u>	
Male	70 (42.2)
Female	96 (57.8)
<u>Age</u>	
Paediatric patient (<18 yrs)	57 (34)
<u>ASA</u>	
ASA1	142 (85.6)
ASA2	11 (6.6)
ASA3	13 (7.8)
<u>Procedure</u>	
Incision and Drainage	56(33.5)
Orthopaedic	31(18.5)
Evacuation of RPOC	28(17.7)
Laceration repair	24(14.4)
Lumbar Puncture	8(4.6)
Other	19(11.3)
<u>Fasting status</u>	
Not fasted, not intoxicated	129(77.7)
Not fasted & intoxicated	8 (4.8)
Fasted	29 (17.5)

Table 2: Breakdown of adverse events and sedation outcome in relation to PSA medication used

	Apnoea	Desaturation (Sats< 93%)	Hallucination	PONV ¹	No complication /total procedures (Percent)	Light sedation (Percent)
Ketofol (1:1 Ketamine+Propofol) + Midazolam +/- N2O	1	0	0	0	5/6 (83.3)	0(0)
Opiate+Midazolam+Ketamine +/- N2O	2	2	1	0	29/34 (85.3)	4(2.4)
Ketamine+Midazolam +/- N2O	0	1	0	1	61/63 (96.8)	4(2.4)
Single agent Midazolam or Ketamine	1	0	0	0	49/50 (98)	2(1.2)
Opiate+Midazolam +/- N2O	0	0	0	0	13/13 (100)	4(2.4)
Total (Percent)	4(2.41)	3(1.81)	1(0.6)	1(0.6)	157/166 (94.6)	14(8.4)

Chi² test: p=0.24; not statistically
significant

PONV= Post operative nausea and
vomiting

Table 3: Adverse events in relation to fasting status and intoxication

Fasting status	No Complications (percent)	Complications (percent)	Total
Not fasted, not intoxicated	123(95.3)	6(4.7)	129
Not fasted and intoxicated	7(87.5)	1(12.5)	8
Fasted	27(93.1)	2(6.9)	29
Total	157(94.6)	9(5.4)	166

Discussion

The South African Department of Health guidelines place the provision of PSA under the responsibility of level 1 hospitals. ⁽⁷⁾

This research was conducted in such a hospital, staffed by medical officers, to determine the outcome of procedural sedation and analgesia (PSA).

The adverse effect rate (Complication rate) overall was low and in keeping with the literature from other countries. ⁽¹¹⁻¹⁴⁾

An unexpected research outcome was detection of a significant difference in side effects in relation to age. The median age of all patients who experienced complications was 40 years versus 23 years in the group of patients that experienced no complications (Two-sample Wilcoxon rank-sum test: $P = 0.0024$).

This might have two reasons. For one, a higher age is known to be a risk factor for anaesthetic complications and complications of PSA ⁽¹⁵⁾.

Most of the paediatric patients received lower doses and fewer PSA drugs. More than one third of all children ($n=22; 38.6\%$) presented for laceration repair while the more painful I&D of abscess was the most common procedure in adults with over 40% of patients attending for this reason ($n=45; 41.28\%$). Laceration repair requires a “lighter” anxiolytic regimen of medication in order for the child to allow infiltration of the affected skin which then fulfils analgesic purpose.

In addition one might find that the attending MO was in general more “careful” when sedating children, and more hesitant to prescribe larger doses or combinations of drugs. In how far this might have led to an under-dosing of the children involved was not examined here and might be a topic for future research.

This trend is reflected in the PSA medication that children and adults received. While the majority of adults (55 out of 109, 50.5%) received Ketamine and Midazolam, most children (42 of 57, 75.4%) had single agents (N₂O; Midazolam, Ketamine or an opiate) for PSA.

A trend was found towards a higher risk of complications with multi drug regimens and addition of Propofol. This is expected as Propofol is well known for its respiratory depressant effect ⁽¹⁶⁾ and a combination of Benzodiazepines and Opiates has been known to cause respiratory side effects ⁽¹⁷⁾.

Future use of this medication combination for PSA will be reviewed. Intoxicated patients were also at an increased risk of adverse effects

Ingestion of alcohol more than doubled complication rate compared to patients who were not intoxicated in this case review series.

While the above findings were not statistically significant, due to small patient numbers, they indicated that guidelines, especially with regards to administration of PSA to intoxicated patients, were not closely followed at all times. While it could be argued that reductions of a dislocated joint would be more difficult after some time has passed and as such should be done as soon as possible (5 of 8 intoxicated patients had dislocated joints), this is definitely not true for incision and drainage of an abscess. (2 of 8 intoxicated patients received PSA for drainage of abscess) These kinds of procedures should be done electively with a fasted and sober patient. One of the eight intoxicated patients suffered side effects by way of a short spell of apnoea. This patient had received a combination of Ketamine and Midazolam for PSA as well as morphine for pain relief by ambulance staff en route to the hospital for a painful dislocated shoulder.

In this case the combination of alcohol, Morphine and Midazolam (with the added Ketamine) predisposed the patient to adverse effects.

There was little difference in complication rate between fasted and not fasted patients. In fact the complication rate in fasted patients was slightly higher at 6.9% than in not-fasted patients who experienced complications in 4.7%. These findings were not statistically significant, due to low overall numbers of complications and low patient rates in both groups.

While for a long time fasting rules have been propagated for PSA as an extension of anaesthesia practice, in recent years applicability of nil per os (NPO) guidelines for PSA have been called into question ^(18,19).

Limitations

While this study was a moderately powered retrospective case review, it lacks the numbers to uncover a serious adverse event. The expected numbers of a sedation

induced death or permanent neurological injury are small-in the order of 1 in tens of thousands. As such much larger patient numbers (in the order of 50000 subjects) would be needed to investigate those events.

Another problem, especially from a patient-centred family physician approach, is the rating of a “successful” procedure. The literature shows us that the rate of sedative failure has been reported inconsistently by different reporters to be as low as 1%-3% ^(20,21) or as high as 10%-20% ^(22,23).

While success rate depends on the setting (including the drugs used, the provider and psychological support as well as presence or absence of a parent in PSA of children) it also depends on the definition used for successful sedation.

In this study PSA was judged to be successful if the procedure could be completed. The condition of the patient was not further described. As such this study would have described a child that received PSA but screamed during the procedure and then slept deeply afterwards as a procedural “success” when in reality it was not.

A patient satisfaction questionnaire is probably the only way to ascertain true “success” of a procedure in a holistic, patient-centred way and more research on PSA should be planned in that way.

Some might feel that lack of a standardized drug regimen was a limitation.

However, the research question was not to prove superiority of a certain drug for provision of PSA but to describe that PSA in general can be safely administered by non-specialised but trained medical staff.

Conclusion:

Procedural sedation and analgesia can be administered safely by Medical Officers in District Hospitals. Future research should expand on PSA research in this setting and focus not just on safety but also on patient satisfaction with PSA.

Newly qualified doctors on South Africa are likely to spend the first few years of their career at district level care. As such the safe provision of PSA is a skill that

should be taught to a wider number of doctors (as a post-graduate course) and even medical students in their undergraduate curriculum.

Adherence to PSA guidelines, knowledge of drugs and basic airway management is of upmost importance.

Most importantly, the relief and avoidance of pain is central to our role as humane professionals and to provision of quality health care.

References

1. Beilin B, Shavit Y, Trabekin E, et al. The effects of post-operative pain management on immune response to surgery. *Anesth Analg* 2003;97(3):822-827.
2. Charmandari E, Kino T, Souvatzoglou E, et al. Pediatric stress: hormonal mediators and human development. *Horm Res* 2003;59(4):161-179.
3. Koga C, Itoh K, Aoki M, et al. Anxiety and pain suppress the natural killer cell activity in oral surgery outpatients. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod*. 2001;91(6):654-658.
4. Hodkinson PW, James MFM, Wallis LA. Emergency department procedural sedation practice in Cape Town, South Africa. *Int J Emerg Med* 2009;2(2):91-97.
5. Matsebula T, Willie M. Private hospitals. In: Harrison S, Bhana R, Ntuli A, eds. *South African Health Review*. Durban: Health Systems Trust, 2007.
6. Department of Health. L1/L2/L3 Acute Hospital Packages of Care. August 2009. Department of Health, Provincial Government of the Western Cape, August 2009.
7. Nkombua L. The practice of medicine at a district hospital emergency room: Middleburg Hospital, Mpumalanga Province. *South African Journal of Family Practice* 2009;50(1):65.
8. American Society of Anesthesiologists. Practice guidelines for sedation and analgesia by nonanaesthesiologists. *Anesthesiology* 2002;96:1004-1017.
9. American College of Emergency Physicians. Clinical policy: procedural sedation and analgesia in the emergency department. *Ann Emerg Med* 2005;45:177-196.
10. American Academy of Pediatrics Committee on Drugs. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. *Pediatrics* 2002;110:836-839.
11. Mensour M, Pineau R, Sahai V, Michaud J. Emergency department procedural sedation and analgesia: A Canadian Community Effectiveness and Safety Study (ACCESS). *CJEM* 2006;8(2):94-99.

12. Roback MG, Wathen JE, Bajaj L, Bothner JP. Adverse events associated with procedural sedation and analgesia in a pediatric emergency department: A comparison of common parenteral drugs. *Acad Emerg Med* 2005;12(6):508-513.
13. Pena BM, Krauss B. Adverse events of procedural sedation and analgesia in a paediatric emergency department. *Ann Emerg Med* 1999;34(4Pt1):483-489.
14. Vardy JM, Dignon N, Mukherjee N, Sami DM, Balachandran G, Taylor S. Audit of the safety and effectiveness of ketamine for procedural sedation in the emergency department. *Emerg Med J* 2008;25:579-582.
15. British National Formulary (BNF) 46, September 2003. London: British Medical Association and Royal Pharmaceutical Society of Great Britain, 2003.
16. Litman RS. Propofol and pediatric sedation (Letter). *Ann Emerg Med* 2004;44:184.
17. Bailey PL, Pace NL, Ashburn MA, Moll JW, East KA, Stanley TH. Frequent hypoxemia and apnea after sedation with midazolam and fentanyl. *Anesthesiology* 1990;73(5):826-830.
18. Agrawal D, Manzi SF, Gupta R, Krauss B. Preprocedural fasting state and adverse events in children undergoing procedural sedation and analgesia in a pediatric emergency department. *Ann Emerg Med* 2003;42:636-646.
19. Green SM. Fasting is a consideration – not a necessity – for emergency department procedural sedation and analgesia. *Ann Emerg Med* 2003;42:647-650.
20. Schwanda AE, Freyer DR, Sanfilippo DJ, et al. Brief unconscious sedation for painful pediatric oncology procedures: intravenous methohexital with appropriate monitoring is safe and effective. *Am J Pediatr Hematol Oncol* 1993;15:370-376.
21. Slonim AD, Ognibene FP. Sedation for pediatric procedures, using ketamine and midazolam, in a primarily adult intensive care unit: a retrospective evaluation. *Crit Care Med* 1998;26:1900-1904.
22. McCarver-May DG, Kang J, Aouthmany M, et al. Comparison of chloral hydrate and midazolam for sedation of neonates for neuroimaging studies. *J Pediatr* 1996;128:573-576.
23. Merola C, Albarracin C, Lebowitz P, et al. An audit of adverse events in children sedated with chloralhydrate or propofol during imaging studies. *Paediatr Anaesth* 1995;5:375-378.

Part D- Supporting documentation

Technical appendices

Age distribution

Age distribution of study participants is further analyzed in figure D1

Fig D1: Age distribution of PSA patients

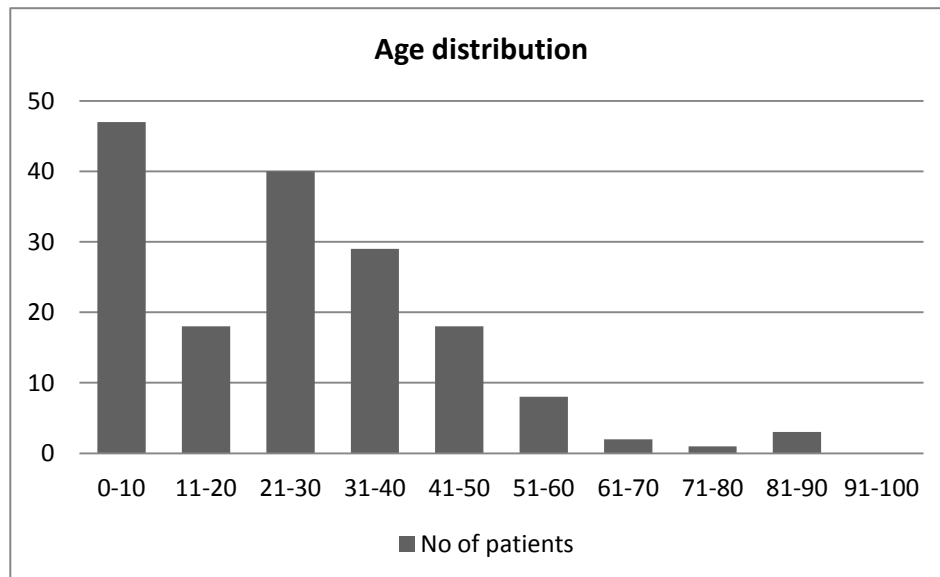
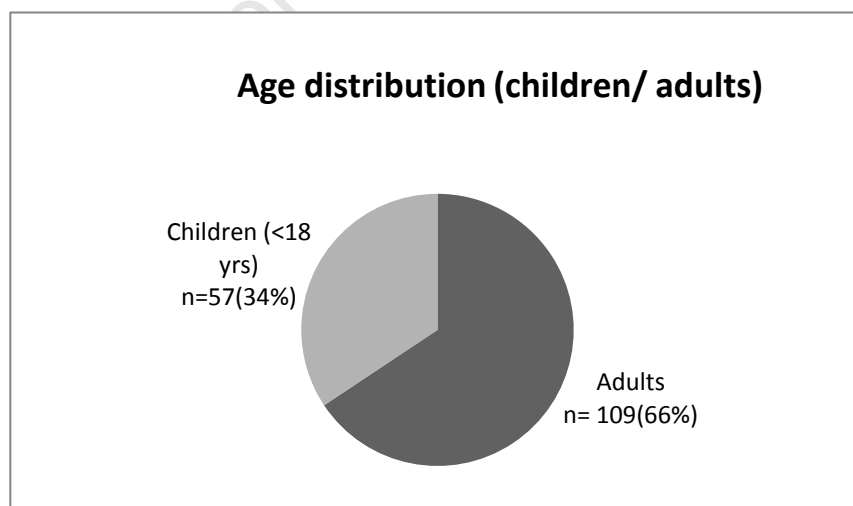


Fig D2: Number of children and adults



Fifty-seven patients or roughly one third of patients were under 18 years of age and 109 patients were adults.

PSA Medication

PSA medication used is outlined below.

There was a significant difference in medication use between children and adults. Children were mainly treated with single agents, while adults were more prone to receive drug combinations, most commonly Ketamine and Midazolam.

Close to 70% of patients were treated with Ketamine and Midazolam either as single agents or combined with addition of N₂O.

Tab 5: PSA medication used (distinguishing between adults and children)

PSA Medication	Adults	Children	Number of patients (n)	Percent
Ketamine+Midazolam +/- N₂O	55	8	63	37.95
Single agent (Midazolam+/- N₂O <u>or</u> N₂O or Ketamine or Opiate)	7	43	50	30.12
Opiate+Midazolam+Ketamine +/- N₂O	32	2	34	20.48
Opiate+Midazolam +/- N₂O	9	4	13	7.83
Ketafol (=Ketamine+Propofol) + Midazolam +/- N₂O	6	0	6	3.61
Total	109	57	166	100

Discharge time

One-hundred forty three patients (86.14%) were discharged following their procedure. The remaining 23 patients were admitted or transferred. The admissions and Transfers were not related to a sedation problem. Discharge time for all PSA patients varied between 10-222 minutes with a mean of 73 (SD = 60.33) minutes.

Sixty percent of patients were discharged within one hour of the procedure and three quarters of the patients were discharged within two hours.

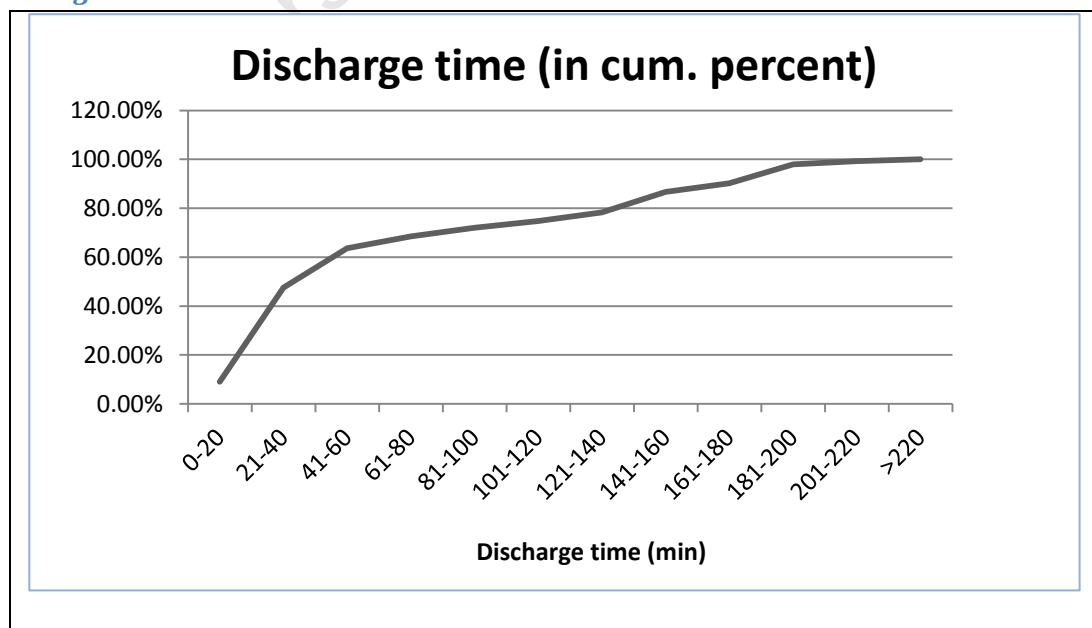
Tab D1: Discharge times (D/C)

Sample size	143patients
Lowest D/C time in minutes	10 min
Highest D/C time in minutes	222 min
Mean D/C time	73 (SD 60.33 min)

Tab D2: Discharge time

Discharge time (min)	Numbers of patients	Percent	Cumulative Numbers	Cumulative percent
0-20	13	9.10	13	9.10
21-40	55	38.46	68	47.55
41-60	23	16.08	91	63.64
61-80	7	4.90	98	68.53
81-100	5	3.50	103	72.03
101-120	4	2.80	107	74.83
121-140	5	3.50	112	78.32
141-160	12	8.40	124	86.71
161-180	5	3.50	129	90.21
181-200	11	7.69	140	97.90
201-220	2	1.40	142	99.30
>220	1	0.70	143	100
Admission	15			
Transfer	8			

Fig D3: Discharge time



Level of sedation

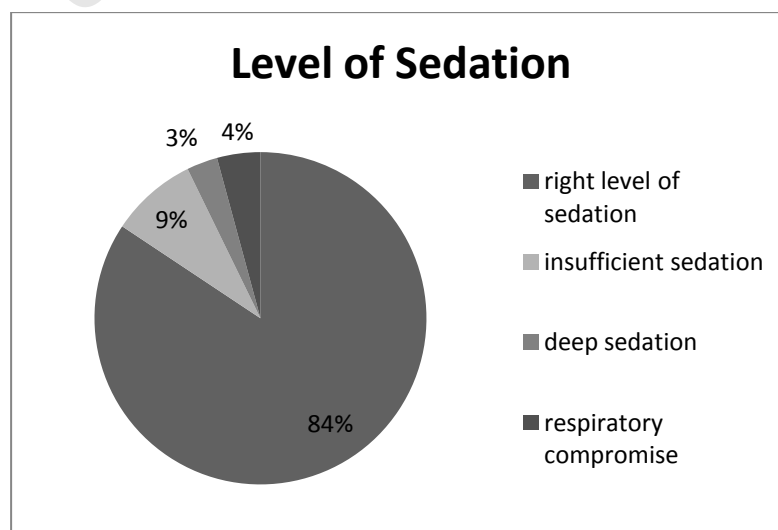
Eighty four percent of patients were sedated to the correct level of sedation for the procedure. Eight percent of patients were insufficiently sedated and experienced pain during the procedure. This might have to do with a numbers of factors like inappropriate drug choices or dosing for the procedure planned or previous drug use of the patient which makes patients susceptible to PSA failure.

Seven percent of patients were too deeply sedated. Three percent experienced mild respiratory side effects.

Tab D2: Level of sedation

Level of sedation	Number	Percent
Correct level of sedation	140	84.33%
Insufficient sedation	14	8.43%
Deep sedation only	5	3.02%
Deep sedation with respiratory compromise (Apnoea/ Desaturation)	7	4.22%
Total	166	100%

Fig D4: Level of sedation achieved



Adverse effects in relation to gender

There was no statistically significant difference between complication rate for male and female patients. ($p>0.05$)

Tab D3: Adverse effects in relation to gender

Adverse effects in relation to gender		
Complication	Female	Male
No complications (Percent)	93 (96.9)	64 (91.4)
Complications (Percent)	3 (3.1)	6 (8.6)
Total (Percent)	96 (100%)	70 (100%)
<i>Fisher's exact: P = 0.169</i>		

Adverse effects in relation to age

Table D4 Adverse effects in relation to age

Complication rate in relation to age in years				
Complication	Number	Median age	Min	Max
No complications	157	22	0.25	88
Complications	9	40	19	81
Total	166	23	0.25	88

Two-sample Wilcoxon rank-sum test: P = 0.0024

There was a statistical difference in the age of the patients that experienced complications versus the age of the patients that did not ($p=0.0024$). The patients that experienced side effects from their treatment were on average older with a

median age of 40 years versus a median age of 22 years for the patients that did not experience side effects.

The youngest patient experiencing adverse effect was 19 years.

University of Cape Town

E mail from SAMJ accepting article for publication

"JP van Niekerk"
<jpvann@hmpg.co.za>

Subject: [SAMJ]
Date: Thu, 02 Jun 2011 18:13:22 +0300
To: "Gisela Wenzel-Smith" <gisela@doctors.org.uk>

Safety and Efficiency of Procedural Sedation and Analgesia (PSA) conducted
by Medical Officers in a Level 1 Hospital in Cape Town

Dear Gisela
The editors have accepted your paper for publication in the SAMJ
Kind regards
JP
South African Medical Journal
<http://www.samj.org.za>

University of

Ethics approval



UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Faculty of Health Sciences Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
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05 August 2010

HREC REF: 361/2010

Dr G Wenzel-Smith
School of Public Health & Family Medicine

Dear Dr Wenzel-Smith

PROJECT TITLE: SAFETY AND EFFICIENCY OF PROCEDURAL SEDATION AND ANALGESIA (PSA) CONDUCTED BY MEDICAL OFFICERS IN A LEVEL 1 HOSPITAL IN CAPE TOWN

Thank you for submitting your study to the Health Science Faculty Research Ethics Committee for review

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Approval is granted for one year till the 15th August 2011.

Please submit a progress form, using the standardised Annual Report Form (FHS016), if the study continues beyond the approval period. Please submit a Standard Closure form (FHS010) if the study is completed within the approval period.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROFESSOR M.BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
sAriefdien

Appendices

PSA form

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Anaesthetic Record

Patient Data Name _____ Age _____ Hospital Number _____		Investigations Date: _____ Hb _____ Platelets _____ INR _____ Date: _____ Na _____ K _____ Urea _____ Creatinine _____ Glucose _____ Date: _____ pH _____ pO ₂ _____ pCO ₂ _____ BE _____ SB _____ FiO ₂ _____																	
History Allergies _____ Medical History _____ Medication _____ Surgical history _____ Diagnosis _____ Proposed Operation _____		CONSENT <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td>Y</td><td>N</td></tr></table> NPO from _____ Smoke _____		Y	N														
Y	N																		
Examination General Weight <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td></tr></table> W and Hb <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td></tr></table> Airway <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td></tr></table> Respiratory <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td></tr></table> Cardiovascular BP <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td></tr></table> / <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td></tr></table> P <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td></tr></table>									ECC _____ CXR _____ <table border="1" style="margin-top: 10px;"> <thead> <tr> <th>FEV₁</th> <th>FVC</th> <th>Ratio</th> </tr> </thead> <tbody> <tr> <td>Pre</td> <td>Post</td> <td>Predicted</td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> Other _____		FEV ₁	FVC	Ratio	Pre	Post	Predicted			
FEV ₁	FVC	Ratio																	
Pre	Post	Predicted																	
Assessment ASA <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td></tr></table>			Notes _____ _____ _____ _____																
Pre-operative Instructions _____ _____																			

Data Capture sheet for Procedural Sedation and Analgesia

[illegible]